

KANECHOM- alcohol antiseptic 80% solution
SNC Indústria de Cosméticos Ltda

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v.

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

169.07 FL.OZ (5L) NDC: 79990-112-05



Kanechom[®]

ALCOHOL ANTISEPTIC 80%

Topical Solution

Hand Sanitizer

Non-sterile Solution

Kills 99.9% of germs

Manufactured by:
SNC Indústria de Cosméticos Ltda.
 R. Aldemiro Fernandes Torres, 1720. CEP: 31780-220.
 B. Jaqueline. Belo Horizonte - MG
www.kanechom.com **MADE IN BRAZIL**
 NDC 79990-112-05



7 893694 002954

Expiration date / Lot.

169.07 FL OZ (5L)

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

Use[s]: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
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Inactive ingredients:
 glycerin, hydrogen peroxide, purified water USP



Kanechom®

ALCOHOL ANTISEPTIC

80%

Topical Solution

Hand Sanitizer
Non-sterile Solution
Kills 99.9% of germs

2.02 FL Oz (60ml)

Drug Facts

Active ingredient Purpose
Alcohol 80% v/vAntiseptic

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Warnings
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Do not use
■ in children less than 2 months of age
■ on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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Drug Facts (continued)

Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing.

Other informations
■ Store between 15-30C (59-86F)
■ Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients:
glycerin, hydrogen peroxide, purified water USP

Manufactured by:
SNC Indústria de Cosméticos Ltda.
R. Aldemiro Fernandes Torres, 1720. CEP: 31780-220.
B. Jaqueline. Belo Horizonte - MG
www.kanechom.com MADE IN BRAZIL
NDC 79990-112-01

Expiration date Lot
7 893694 002992



Kanechom®

ALCOHOL ANTISEPTIC

80%

Topical Solution

Hand Sanitizer
Non-sterile Solution
Kills 99.9% of germs

3.38 FL Oz (100ml)

Drug Facts

Active ingredient Purpose
Alcohol 80% v/vAntiseptic

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Warnings
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Do not use
■ in children less than 2 months of age
■ on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. ➡

Drug Facts (continued)

Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing.

Other informations
■ Store between 15-30C (59-86F)
■ Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients:
glycerin, hydrogen peroxide, purified water USP

Manufactured by:
SNC Indústria de Cosméticos Ltda.
R. Aldemiro Fernandes Torres, 1720. CEP: 31780-220.
B. Jaqueline. Belo Horizonte - MG
www.kanechom.com MADE IN BRAZIL
NDC 79990-112-02

Expiration date Lot
7 893694 002985





Kanechom[®]
ALCOHOL ANTISEPTIC
80%
Topical Solution

Hand Sanitizer

Non-sterile Solution

Kills 99.9% of germs

8.45 FL Oz (250ml)

Drug Facts

Active ingredient Purpose

Alcohol 80% v/vAntiseptic

Use[s]: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

**For external use only. Flammable.
Keep away from heat or flame.**

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out

Drug Facts (continued)

Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing.

Other informations

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients:

glycerin, hydrogen peroxide, purified water USP

when using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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purified water 001

Manufactured by: SNC Indústria de Cosméticos Ltda.
R. Aldemiro Fernandes Torres, 1720. CEP: 31780-220.
B. Jaqueline. Belo Horizonte - MG
www.kanechom.com MADE IN BRAZIL
NDC 79990-112-03

Expiration date

Lot





Kanechom[®]
**ALCOHOL
 ANTISEPTIC
 80%**
Topical Solution

Hand Sanitizer
 Non-sterile Solution

Kills 99.9% of germs

16.9 FL Oz (500ml)

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

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 ■ in children less than 2 months of age
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 ■ Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients:
 glycerin, hydrogen peroxide, purified water USP

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 R. Aldemiro Fernandes Torres, 1720. CEP: 31780-220.
 B. Jaqueline. Belo Horizonte - MG
 www.kanechom.com MADE IN BRAZIL
 NDC 79990-112-04
 Expiration date / Lot.



KANECHOM
 alcohol antiseptic 80% solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79990-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		1.450 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0K00R)		18.425 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79990-112-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
2	NDC:79990-112-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
3	NDC:79990-112-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
4	NDC:79990-112-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
5	NDC:79990-112-05	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/03/2020		

Labeler - SNC Indústria de Cosméticos Ltda (914610642)

Establishment

Name	Address	ID/FEI	Business Operations
SNC Indústria de Cosméticos Ltda		914610642	manufacture(79990-112)

Revised: 8/2020

SNC Indústria de Cosméticos Ltda